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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/063,978	04/21/98	OBREMSKI	R 45D-1750 (641)

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HM12/0901

EXAMINER

HINES, J

ART UNIT	PAPER NUMBER
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1645

DATE MAILED:

09/01/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/063,978

Applicant(s)

Obremski et al.

Examiner

Ja-Na Hines

Group Art Unit
1645



☒ Responsive to communication(s) filed on Jul 5, 2000

☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-26 is/are pending in the application

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-26 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

1. Claims 1-26 are pending in the Office Action.

Drawings

2. The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on June 27, 2000 have been accepted.

Response to Arguments

3. Applicant's arguments filed July 5, 2000 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-4, 13-19, 21 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ekins et al., (EP 304,202) in view of Ekins et al., (J. of Clinical Immuno.) Is maintained. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. However Ekins et al., (EP 304,202) does not teach the analyte being

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substantially depleted from the sample, however Ekins et al., (J. of Clinical Immuno.) teaches analyte binding by antibody clearly causes analyte depletion in the surrounding medium.

Therefore, at the time of applicants invention it would have been obvious to use the technique of allowing for analyte depletion in a sample as taught by Ekins et al., (J. of Clinical Immun.) in the binding assay of Ekins et al., (EP 304,202) because this technique is already well known in the art for determining analyte concentration.

5. Claims 1-4, 13-19, 21 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ekins et al., (EP 304,202) in view of Ekins et al., (Analytica Chimica Acta.) Is maintained. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In this case, Ekins et al., (EP 304,202) has been discussed above. Ekins et al., (Analytica Chimica Acta.) teaches the analyte binding by antibody clearly causes analyte depletion in the surrounding medium. Further, no more than routine skill is required to implement well known techniques such as analyte depletion into the binding assay of Ekins et al. (EP 304,202). Thus, at the time of applicants invention it would have been obvious to use the technique of allowing for analyte depletion in a sample as taught by Ekins et al., (Analytica Chimica Acta.) in the binding assay of Ekins et al., (EP

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304,202) because this technique is already well known in the art for determining analyte concentration.

6. Claims 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ekins et al., (EP 304,202) and either Ekins et al., (J. of Clinical Immuno.) or Ekins et al., (Analytica Chimica Acta.), in further view of Ullman et al., (US Patent 5,512,659) is maintained. Applicant's argue that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In this case, Ekins et al.(EP 304,202), Ekins et al., (J. of Clinical Immuno.) and Ekins et al., (Analytica Chimica Acta.) have been discussed previously. Therefore, it would have been obvious at the time of applicants invention to have used the first binding partner, conjugate, biotin-avidin labels and biotinylated antibodies as taught by Ullman et al., in the method of Ekins et al., (EP 304,202) in view of either Ekins et al., (J. of Clinical Immuno.) or Ekins et al., (Analytica Chimica Acta.) because Ullman et al., teaches that these methods are more versatile and convenient than the known methods.

7. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ekins et al., (EP 304,202), in view of either Ekins et al., (J. of Clinical Immuno.) or Ekins et al., (Analytica

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Chimica Acta.) in further view of Waggoner et al., US Patent (5,368,486) is maintained. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. The Ekins et al., references have been discussed previously however, none of the three Ekins et al., references teach the use of cyanine dyes. Waggoner et al., (US Patent 5,268,486) teaches the use of fluorescent cyanine and related polymethine dyes which can be used for detecting the presence of certain proteins. No more than routine skill would have been required to use cyanine dyes as taught by Waggoner et al., in the method of Ekins et al., (EP 304,202) in view of either Ekins et al., (J. of Clinical Immuno.) or Ekins et al., (Analytica Chimica Acta.) because Waggoner et al., teaches that these cyanine dyes are intrinsically more fluorescent; have improved photostability; improved water solubility; can label a wide variety of biological materials; and subject to a variety of excitation wavelengths using lasers.

8. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ekins et al., (EP 304,202) in view of either Ekins et al., (J. of Clinical Immuno.) or Ekins et al., (Analytica Chimica Acta.) in view of Waggoner et al., US Patent (5,368,486) in further view of Lee et al., (US Patent 5,453,505) is maintained. Ekins et al., (EP 304,202), Ekins et al., (J. of Clinical

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Immuno.), Ekins et al., (Analytica Chimica Acta.) and Waggoner et al., have all been discussed previously however, none teaches the use of Cy5 or Cy7. In this case, applicants argue that there is no suggestion to combine the references, however the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. Lee et al., teaches the most stable dye was found to be the dye with the shortest wavelength, Cy5 whose structure contains five methine groups, while the remaining dyes contain seven methine groups, such as Cy7 which has similar stability. Accordingly, it would have been obvious at the time of applicants invention to have used Cy5 or Cy7 as taught by Lee et al., in the method of Ekins et al., (EP 304,202) in view of either Ekins et al., (J. of Clinical Immuno.) or Ekins et al., (Analytica Chimica Acta.), and Waggoner et al., US Patent (5,368,486), because Lee et al., teaches a reduced tendency to aggregate and enhanced photostability.

9. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ekins et al., (EP 304,202) in view of either Ekins et al., (J. of Clinical Immuno.) or Ekins et al., (Analytica Chimica Acta.) in view of Northrup et al (US Patent 5,639,423) is maintained. Ekins et al., (EP 304,202) in view of either Ekins et al., (J. of Clinical Immuno.) or Ekins et al., (Analytica Chimica Acta.) have been discussed previously. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be

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established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In this case, it would have been obvious at the time of applicants invention to use the well known method of dispensing material using a jet printer as taught by Northup et al., in the method of Ekins et al., (EP 304,202) in view of either Ekins et al., (J. of Clinical Immuno.) or Ekins et al., (Analytica Chimica Acta.) because Northup et al., teaches that the method is especially advantageous for biochemical reactions.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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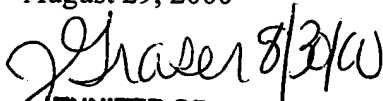
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines 

August 29, 2000


JENNIFER GRASER
PATENT EXAMINER